Remarks

Reconsideration of this Application is respectfully requested.

Upon entry of the foregoing amendment, claims 18-47 are pending in the application, with 18, 22, 26 and 29 being the independent claims.

Based on the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

Support for new claim 47 can be found throughout the application, and specifically at pages 2, 5 and 6.

I. Rejection Under 35 U.S.C. § 102

Claims 18, 19, 26, 27, 29, and 30 are rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent 5,234,695 to Hobbs *et al.* ('695 patent). The Examiner asserts that the '695 patent discloses a vitamin E composition comprising a free-flowing powder containing a vitamin E compound, and at least one flow agent selected from silicon dioxide, starch and others. Office Action (OA) at page 2. The Examiner also asserts that the '695 patent teaches that the vitamin E compound is present in an amount between 20-60% by weight of the composition. *See Id.* After consideration of Applicants' amendment of the claims to recite compositions free of fatty acid esters of glycerine, the Examiner has maintained the rejection and has shifted the burden to the Applicants to establish, in declaration form, that said fatty acid esters of glycerine are detrimental to said formulation. OA at page 3.

The Manual of Patent Examining Procedure ("MPEP") §2131 describes the application of 35 U.S.C. §102(b). A claim is anticipated only if each element as recited in the claim is found, expressly or inherently described, in a single prior art reference. MPEP §2131, citing *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The standard for anticipation or lack of novelty is one of strict identity. To anticipate a claim for a patent, a single prior art source must contain all of its essential elements or limitations. *Kloster Speedsteel AB v. Crucible, Inc.*, 793 F.2d 1565, 230 U.S.P.Q. 81 (Fed. Cir. 1986), *cert. denied*, 479 U.S. 1034 (1987) (citing treatise). A negative limitation is considered an element of a claim. The use of a negative limitation to define the metes and bounds of the claimed subject matter is a permissible form of expression. *See In re Wakefield*, 57 C.C.P.A. 959, 422 F.2d 897, 164 U.S.P.Q. 636 (1970) (claim with "negative limitation" excluding the characteristics of the prior art products" is "still definite...because such recited limitation is definite.")

The '695 patent discloses a vitamin E composition comprising at least one fatty acid ester of glycerine. Applicants' composition specifically excludes fatty acid esters of glycerine. Although the Examiner has shifted the burden to Applicants to establish, in declaration form, that fatty acid esters of glycerine are detrimental to the recited formulation, Examiner has not pointed to any authority which permits such a shifting of the burden or requires this type of support. In fact, the Board of Patent Appeals and Interferences has stated, "[i]t is incumbent upon the examiner to identify wherein each and every facet of the claimed invention is disclosed in the applied reference. *Ex parte Levy*, 17 USPQ2d 1461, 1462 (Bd. Pat. App. & Int'f 1990). The Examiner's request for evidence showing that fatty acid esters of glycerine are detrimental to Applicants'

invention is essentially a request for the motivation or reasoning for omitting this element from the claimed invention. Motivation is not a consideration in an anticipation analysis. It is irrelevant whether the fatty acid esters of glycerine are detrimental to Applicants' composition because the Federal Circuit has stated that anticipation is only established when there is strict identity between the elements of the patent claim and the prior invention. *See Finnigan Corp. v. United States Int'l Trade Comm'n*, 180 F.3d 1354, 1365-66, 51 USPQ2d 1001, 1008 (Fed. Cir. 1999). Thus, because not all the elements of the Applicants' claims have been met by the disclosure in the '695 patent, the Examiner has not established a *prima facie* case of anticipation and Applicants' invention is novel over the prior art. Applicants request that the rejection be withdrawn.

II. Rejections under 35 U.S.C. § 103

A. Schmidt (U.S. Patent No. 4,603,143)

The Examiner has rejected claims 18-46 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent 4,603,143 to Schmidt ("US '143"), stating that US '143 teaches that the composition comprises at least one fat-soluble vitamin material and a silicon-containing material. Additionally, the Examiner asserts that US '143 teaches that the silicon dioxide used in their composition has a density of around 0.2 g/cc (12.5 lbs./cu.ft.), and a particle size which passes through a 100 mesh sieve (particles smaller than 150 microns). The burden was shifted to the Applicants to show that the silica (silicon dioxide) disclosed by US '143 does not possess the same characteristics as the silica claimed by the Applicants.

Applicants assert that the use of silica that is 40 to 50 microns in length is critical to obtain the desired properties of the claimed invention. *See* §1.132 Morris Declaration.

One of ordinary skill in the art would expect that the use of silica within the range of 40-50 microns to result in an end product that is not a free-flowing powder due to insufficient absorption of the liquid tocopherols and agglomeration of the particles. *See Id.* The data contained in **Exhibit B** and described in the §1.132 Morris Declaration provides support for this assertion because silica outside the 40 to 50 micron size range produced vitamin powders which were "chunky" or "gritty." Based on this data, one of ordinary skill in the art would have expected powders produced with silica having a particle size between 40-50 microns to also be "chunky" or "gritty" instead of free-flowing. Silica within the 40-50 micron size range unexpectedly allowed for the absorption of liquid tocopherols at a high rate while still maintaining the free-flowing properties that are crucial to the claimed invention.

The upper silica particle size limit of 50 microns is supported by the data summarized in Item 9 of the §1.132 Morris Declaration, which shows that Sipernat 50 had good oil absorption and produced an end product that was "smooth" and acceptable for processing. The test results for silica with a particle size that is larger than 50, Sipernat 22 (100 microns) showed very poor oil absorption, and production of a "chunky" vitamin powder that was not acceptable for processing. *See* **Exhibit B**. The data represented in the Morris §1.132 Declaration and **Exhibit B** does not show any silica with a particle size larger than 50 microns that produced smooth vitamin powders that were acceptable for processing. Therefore, 50 microns is the appropriate upper limit of the size range of silica particles for production of the free-flowing vitamin powders of the present invention.

The lower silica particle size limit of 40 is also supported by **Exhibit B**, which shows that Aerosil R 972 (16 microns), produced a "very gritty" powder that was not acceptable for processing, whereas Sipernat 50, (50 microns), produced a "smooth" vitamin powder that is acceptable for processing. *See also* Morris §1.132 Declaration, Item 9. The lower particle size limit of 40 microns is supported by this data because the size difference between 40 microns and 16 microns (24 microns) is more than double the difference between 40 and 50 (10 microns). Based on this data, silica that is 40 microns will produce a "smooth" powder that is acceptable for processing as was produced with the Sipernat 50, and not a "very gritty" powder that is unacceptable for processing as was produced with the Aerosil R 972. Thus, 40 microns is the appropriate lower limit for silica particles to produce the free-flowing vitamin powders of the present invention.

Because it was unexpected that the 40-50 micron silica particle size range was so critical to successful production of the free-flowing vitamin powders of the present invention, the invention is not obvious and the rejection under 35 U.S.C. §103(a) has been overcome. Applicants request that the rejection be withdrawn.

B. Hobbs et al. (U.S. Patent No. 5,234,695)

The Examiner has rejected claims 18-46 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent 5,234,695 to Hobbs *et al.* ("US '695"), stating that US '695 teaches a vitamin E composition comprising a free-flowing powder containing between 20-60% of a vitamin E compound and at least one flow agent selected from a group including silicon dioxide and starch. The Examiner states that one of ordinary skill in the art would have been motivated to make a vitamin composition comprising vitamin E, silica, and corn starch based on the teachings of US '695, and that the result would be a

free-flowing, non-sticking powder useful for pharmaceutical formulations. Applicants respectfully traverse this rejection.

US '695 discloses a water dispersible vitamin E composition, which requires at least one fatty acid ester of glycerine to obtain the desired properties. This element is essential to obtain the properties of the free-flowing, water soluble vitamin E compound disclosed in US '695. US '695 states, "[t]he composition of the present invention is a free flowing powder comprising a water soluble vitamin E compound and a material having an overall melting point of at least about 30°C., containing *at least one fatty acid ester of glycerine.*" *See* U.S. '695, column 1, lines 64-68 (*emphasis added.*) There is no suggestion or motivation in U.S. '695 to omit this essential element, and its importance is further emphasized by the extensive discussion of its role in the composition. (e.g., column 2, line 66 to column 3, line 49.) Thus, U.S. '695 teaches away from preparing a free-flowing vitamin E composition comprising a vitamin E compound, silica and a flow agent free of fatty acid esters of glycerine. Such a composition would not be expected to exhibit the properties described in U.S. '695 without the inclusion of the essential element of fatty acid esters of glycerine. Therefore, Applicants' free-flowing vitamin powder excluding fatty acid esters of glycerine is not obvious. Applicants submit that the rejection of claims 18-46 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent 5,234,695 to Hobbs *et al.* has been overcome by the production of a free-flowing vitamin powder which excludes fatty acid esters of glycerine. Applicants request that the rejection be withdrawn.

Conclusion

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

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